NATIONAL INSTITUTES OF HEALTH

FISCAL YEAR 2003

PLAN FOR HIV-RELATED RESEARCH

I: OVERVIEW

PREPARED BY THE OFFICE OF AIDS RESEARCH

Foreword

As the Acting Director of the Office of AIDS Research (OAR), I am pleased to present the National Institutes of Health (NIH) Fiscal Year 2003 Plan for HIV-Related Research. Each year, we develop a comprehensive research plan based on broad consensus within the community of scientists and other experts. This collaborative process involves many individuals, including scientists from academia and industry; representatives of foundations and other nongovernmental organizations; community representatives; representatives of other Governmental agencies; and Directors of the NIH Institutes and their staff. The contributions of this diverse group of experts are crucial to the planning process, and I am grateful to each of them for the time and careful consideration that they gave to the development of this Plan.

It is our intent that the Plan be responsive to the changing face of the epidemic, to emerging scientific opportunities, and to the needs of the affected community. Thus, we have continued to expand the scope of the Plan over the last few years. This year, compelling evidence prompted us to add three new Areas of Emphasis to the Plan to more completely describe our research plans for development of microbicides, HIV prevention research, and research related to women and girls and HIV. It is our hope that this increased focus will stimulate research in these areas. The transmissible nature of HIV makes it fundamentally different from nontransmissible diseases such as heart disease and cancer. This characteristic provides the potential for limiting the spread, and there is a broadly recognized need and urgency to expand the range of preventive interventions

for HIV transmission. The many approaches include behavioral and social interventions, biomedical approaches, and vaccines. Although NIH continues to give high priority to the development of vaccines for HIV, it is acknowledged that even when a vaccine becomes available, it will be one of many approaches used to slow and halt the epidemic. With this recognition, we determined the need to include a section that focuses attention on the myriad nonvaccine approaches to prevention.

In the context of the current status of the epidemic, both in the United States and around the world, it is critical that prevention methods be developed that can be controlled by women to prevent becoming infected. Microbicides (agents that can be applied topically for the prevention of sexually transmitted diseases, including HIV) may offer one of the most promising preventive interventions that could be safe, effective, inexpensive, readily available, and widely acceptable. However, many scientific challenges remain in the development and testing of microbicide candidates. To more specifically identify research needs to address these challenges, we have developed a plan for research on microbicides, included here in the FY 2003 Plan.

As the epidemic in the United States continues to evolve, women are becoming increasingly affected by HIV, with women currently representing an estimated 30 percent of new infections. Globally, women comprise approximately 47 percent of 35 million people living with HIV. Although women of all ages are affected, women of childbearing years reflect the highest prevalence of infection. Around the world, young girls are particularly vulnerable for biological, cultural, and economic reasons, and concerns mount for this population in the United States and abroad. Women and girls also are affected differently by AIDS because of their roles in the family and in society. Because of the complex nature of HIV infection in women and girls, we have worked to identify specific research questions to address the special biological, social, and cultural issues for these populations, which are outlined in this new section of the Plan.

In the United States, the AIDS epidemic continues to devastate minority communities, and racial and ethnic minorities dominate both new AIDS cases and new infections. Seroprevalence rates among racial and ethnic minorities in some urban centers mimic those in the developing world. This disproportionate impact has presented significant challenges to biomedical, behavioral, social, and clinical research. The interplay of cultural, economic, political, individual, and societal factors requires comprehensive and innovative interventions. The need to develop such interventions is tightly linked to the need to strengthen research at minority

institutions and to increase the number of minority investigators. Toward this end, we have described a multifaceted approach to addressing these issues in the section on racial and ethnic minorities.

Globally, concern has intensified about the continuing increase in the pandemic. In June 2001, the United Nations called a Special Session of the General Assembly to discuss a coordinated, intensified response by the nations of the world to the global emergency created by AIDS. Research to address this pandemic is essential, and we at NIH are committed to expanding our research portfolio that is designed to provide useful information for the development of programs and approaches in resource-poor settings to prevent new infections, to care for those infected, and to assist families and communities affected by HIV. This research agenda is described in the section on international research.

We also continue our commitment to research to define the nature of disease progression, develop therapies for HIV infection and related conditions, and develop vaccine candidates. Integral to this effort is the conduct of basic research to define pathogenic mechanisms and identify therapeutic and vaccine strategies at the cellular and molecular levels. Thus, the FY 2003 Plan also includes the "traditional" Areas of Emphasis that have comprised the Plan since its inception. The sections of the Plan are intended to be mutually reinforcing, and thus specific activities may be described in more than one section, reflecting the efforts of our groups of experts to ensure that the NIH Plan is comprehensive.

The Plan serves as the framework for the development of the NIH AIDS budget, and thus is an invaluable tool in guiding our investment in research to address HIV and AIDS. We sincerely believe that the efforts described here will result in further strides in developing new interventions to prevent the spread of infection, new treatments to alleviate physical suffering, and new approaches to assist families and communities affected by HIV.

Jack Whitescarver, Ph.D.
Acting Director, OAR
September 2001

Legislative Mandate

The National Institutes of Health Revitalization Act of 1993 (Public Law 103-43) provided that the Director of the Office of AIDS Research (OAR) "shall plan, coordinate and evaluate research and other activities conducted or supported" by NIH. The Director of OAR "shall act as the primary Federal official with responsibility for overseeing all AIDS research conducted or supported by the National Institutes of Health" and shall "establish a comprehensive plan for the conduct and support of all AIDS activities of the agencies of the National Institutes of Health...; ensure that the Plan establishes priorities among the AIDS activities that such agencies are authorized to carry out; ensure that the Plan establishes objectives regarding such activities...; and ensure that the Plan serves as a broad, binding statement of policies regarding AIDS activities of the agencies, but does not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the Plan." The law further provides that "the Director of the Office shall ensure that the Plan provides for basic research; provides for applied research; provides for research that is supported and conducted by the agencies; provides for proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and provides for behavioral research and social science research."

Table of Contents

Introduction

THE EXPLODING GLOBAL HIV/AIDS PANDEMIC

By every definition, AIDS is the great plague of the 20th century. HIV has infected more than 50 million people around the world. AIDS already has killed more than 21 million people, surpassing tuberculosis and malaria as the leading infectious cause of death worldwide, according to data released by the Joint United Nations Programme on HIV/AIDS (UNAIDS) in the "AIDS Epidemic Update: December 2000" and the World Health Report 2000 of the World Health Organization (WHO).

The Exploding Global HIV/AIDS Pandemic

Group	People Newly Infected in 2000	People Living with HIV/AIDS	AIDS Deaths in 2000	Total AIDS Deaths
Adults	4.7 Million	34.7 Million	2.5 Million	17.5 Million
Women	*2.2 Million*	*16.4 Million*	*1.3 Million*	*9.0 Million*
Children	600,000	1.4 Million	500,000	4.3 Million
Total	**5.3 Million**	**36.1 Million**	**3.0 Million**	**21.8 Million**

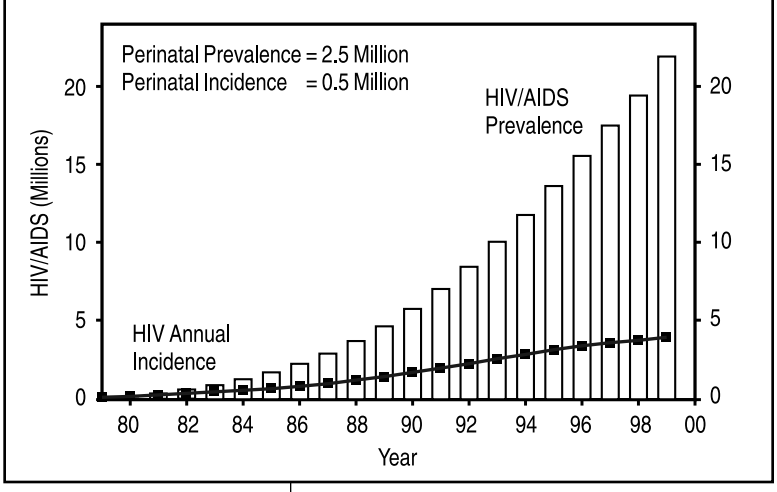
Source: UNAIDS

The seriousness of the crisis was dramatized in June 2001 when the United Nations convened a Special Session of the General Assembly to address HIV/AIDS. A significant event was the establishment of a Global Trust Fund for AIDS, to which the industrialized nations of the world are contributing.

If the global spread of HIV/AIDS continues unchecked, South and Southeast Asia, and perhaps China will follow the disastrous course of sub-Saharan Africa. Currently, there are an estimated 5.8 million HIV-infected people in South and Southeast Asia. In India alone, UNAIDS estimates that between 3 and 5 million of its nearly 1 billion population are infected, and the number of new infections is continuing to double every 14 months. Rapid increases in the number of new infections also are occurring in Eastern Europe and Central Asia, and AIDS remains a serious threat in Latin America and the Caribbean. During the year 2000, more new HIV infections will have been registered than in all previous years of the epidemic combined in the Russian Federation.

Recent data indicate that worldwide there are now almost equal numbers of men and women infected with HIV. In sub-Saharan African, UNAIDS/WHO estimated that more women than men were living with HIV/AIDS at the end of 1999: 12.2 million women and 10.1 million men between the ages of 15-49. Curbing the transmission of HIV from infected mother to infant is an especially compelling challenge in developing countries.

HIV Incidence and HIV/AIDS Prevalence, Sub-Saharan Africa, 1980–1999



Source: UNAIDS, 1999

The coexistence of other endemic diseases widely prevalent in developing countries, such as respiratory and gastrointestinal infections, complicate treatment and pose additional problems for medical personnel caring for HIV-infected individuals. Of particular note is the parallel epidemic of tuberculosis in the developing world. Attitudes, beliefs, and taboos surrounding sex, the status of women and children, and the source and etiology of AIDS can complicate attempts to control transmission and provide appropriate prevention and treatment.

THE HIV/AIDS EPIDEMIC IN THE UNITED STATES

In the United States, the HIV/AIDS epidemic continues to evolve. Although the incidence of new AIDS cases has declined, attributed largely to expanded use of new antiretroviral therapies that prevent progression of HIV infection to AIDS, the decline in death rates observed in the late 1990s has leveled off. Further, according to the Centers for Disease Control and Prevention (CDC), the rate of new HIV infections has been constant at approximately 40,000 new cases each year since 1990, meaning that the

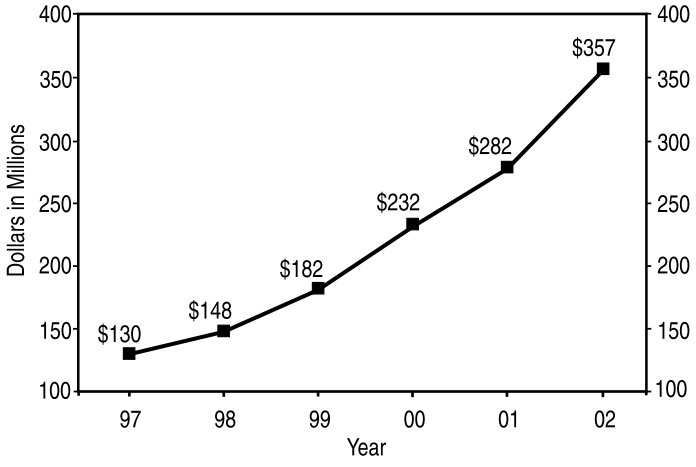
overall epidemic is continuing to expand. In fact, HIV infection rates are continuing to climb in a number of subpopulation groups, such as women, racial and ethnic minorities, young homosexual men, individuals with addictive disorders, and people over 50 years of age. The recent appearance of multi-drug resistant strains of HIV presents a serious public health concern. These data forebode an epidemic of even greater magnitude in the coming years.

AIDS disproportionately affects African Americans and Hispanics. They account for 48 percent and 20 percent, respectively, of all persons newly diagnosed with AIDS during 1999. CDC's HIV/AIDS Surveillance Report of September 2001 states that among women with AIDS, minorities account for 83 percent of cases; among men, minorities account for 66 percent of cases. Addressing these racial disparities is a high priority for the NIH.

THE NIH AIDS RESEARCH AGENDA

In response to this pandemic, NIH has developed a comprehensive biomedical and behavioral research program to better understand the basic biology of HIV, develop effective therapies to treat it, and design interventions to prevent new infections from occurring. It is the role of the Office of AIDS Research (OAR) to plan and coordinate this research program sponsored by all of the NIH Institutes and Centers. The changing demographics in the epidemic demand careful consideration in planning our research agenda, since different prevention and intervention strategies must be applied to each subepidemic.

Funding for Vaccine Research



Source: NIH, 2001

Four major themes frame the FY 2003 Research Plan: prevention research to reduce HIV transmission here in the United States and around the world; therapeutic research to treat those who are already infected; international research priorities, particularly to address needs in developing countries; and research targeting the disproportionate impact of AIDS on minority populations in the United States. All of these efforts require a strong foundation of basic science.

Prevention Research

The transmissible nature of HIV makes it radically different from nontransmissible diseases such as heart disease and cancer. The transmissibility of HIV—between individuals and across borders and populations—is what most defines the global pandemic and makes it imperative that the United States help address prevention and treatment needs worldwide. The transmissibility of the infection means that there is the potential for unlimited global spread. But it also means that, with the development of appropriate biomedical and behavioral interventions, there is the possibility for dramatic reductions in new infections—and ultimate control of the pandemic—in a way that will not be possible for noninfectious diseases.

NIH supports a comprehensive approach to HIV prevention research that includes contributions from the biomedical, behavioral, and social sciences. The OAR prevention science research agenda targets interventions to both infected and uninfected at-risk individuals to reduce HIV transmission. Our biomedical prevention research priorities include the development of topical microbicides, strategies to prevent perinatal transmission (including a better understanding of risk associated with breast-feeding), and management of sexually transmitted diseases. NIH also supports behavioral research strategies, including prevention interventions related to drug and alcohol use and risky sexual behaviors. Efforts continue to identify the most appropriate intervention strategies for different populations and sub-epidemics in the United States and around the world. The OAR Prevention Science Working Group continues to provide advice about HIV prevention research priorities.

Vaccine Research

A safe and effective HIV preventive vaccine is essential for the global control of the AIDS pandemic. NIH funding for HIV vaccine research increased by more than 170 percent between FY1997 and FY2002, resulting in the award of new grants to foster innovative research on HIV vaccines, including vaccine design and development, and the invigoration and reorganization of the NIH vaccine clinical trials effort. Construction of the new intramural Vaccine Research Center has been completed. In February 1999, NIH-supported investigators initiated the first AIDS vaccine trial in Africa. The AIDS Vaccine Research Committee, chaired by Nobel laureate Dr. David Baltimore, continues to provide critical advice on all aspects of the NIH AIDS vaccine development program. The changes implemented in this area over the past few years have enormous significance, not only for AIDS

research but for other diseases as well, as progress made in the development of an AIDS vaccine will have implications for vaccines against other life-threatening illnesses.

Behavioral and Social Science Research

Studies have demonstrated that behavioral change can successfully prevent or reduce the spread of HIV infection in both domestic and international settings. Prevention programs resulting from such studies have altered sexual and drug-using behaviors and have reduced the risk of transmission in many communities and subgroups. NIH supports research to further our understanding of how to change the behaviors that lead to HIV transmission—including preventing their initiation—and how to maintain protective behaviors once they are adopted in all populations at risk. NIH also supports research on preventing and mitigating the psychosocial consequences of HIV/AIDS on individuals and communities.

Topical Microbicides Research

The vulnerability of women to acquiring HIV infection demands the development of effective and acceptable female-controlled chemical and physical barrier methods, such as topical microbicides, to reduce HIV transmission. To enhance and stimulate research in this area, OAR co-sponsored the first international conference devoted to all aspects of microbicide research and development. The conference, Microbicides 2000, included more than 600 participants from 45 nations. NIH is supporting Phase I, Phase II, and Phase III trials of various topical microbicides. NIH also supports behavioral and social research on the acceptability and use of microbicides among different populations. Additional efforts are essential to accelerate microbicides research and to ensure a comprehensive program for screening, discovery, development, preclinical testing, and clinical evaluation of potential spermicidal and nonspermicidal topical agents and other barrier methods. To that end, OAR has now prepared the first strategic plan for microbicide research.

Mother-to-Child Transmission

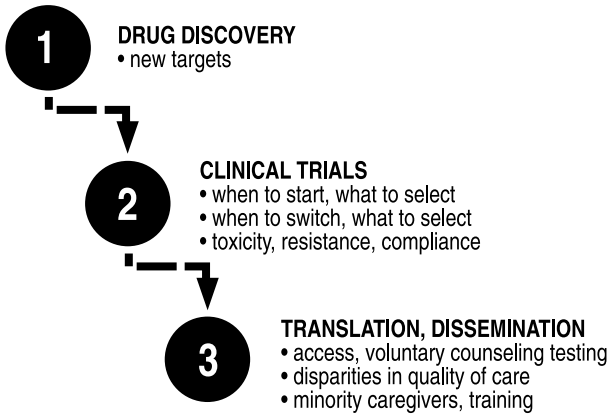
In the United States, regimens of antiretroviral drugs resulting from NIH-supported research have dramatically reduced transmission from infected mother to infant. However, the complexity of administration and high cost make this option impractical for much of the developing world. For example, NIH-supported clinical trials in Uganda recently demonstrated that a single dose of the nonnucleoside reverse transcriptase inhibitor

nevirapine—given to women during labor and followed by a single dose administered to their newborns, at a total cost of approximately $4—reduced transmission by half, compared with a similar and considerably more costly short course of AZT. This advance can substantially lower the cost barrier that has kept many countries from adopting drug strategies that prevent perinatal HIV transmission. However, lack of health care infrastructure or access to other health care services may still affect the ability of developing countries to implement this regimen. Further research on this and other low-cost alternatives is included in this plan. Another key research issue is the need for better methods for the reduction of HIV transmission through breast-feeding.

Treatment Research

The development of therapeutics for HIV/AIDS has long been a focus of NIH. Today, many HIV-infected people are living with the benefits resulting from NIH-supported research in this area. The development of combination regimens including protease inhibitors has extended the length and quality of life for many HIV-infected individuals in the United States and Western Europe. Unfortunately, however, highly active antiretroviral therapy (HAART) has failed to eradicate HIV, and a growing proportion of patients receiving therapy experience treatment failure. Some patients find it difficult or impossible to comply with arduous treatment regimens, develop toxicities and side-effects, or cannot afford the high cost of approximately $15,000 per year. Others fail to obtain a satisfactory reduction in viral load even while adhering to treatment regimens. In addition, metabolic complications, including insulin resistance, and body composition changes, such as deforming deposits of abdominal adipose tissue, have emerged in individuals who have been on long-term antiretroviral regimens. Finally, an increasing number of treatment failures are linked to the increasing emergence of drug-resistant HIV.

AIDS Therapy:
Drug Discovery and Clinical Trials



Source: NIH, 2001

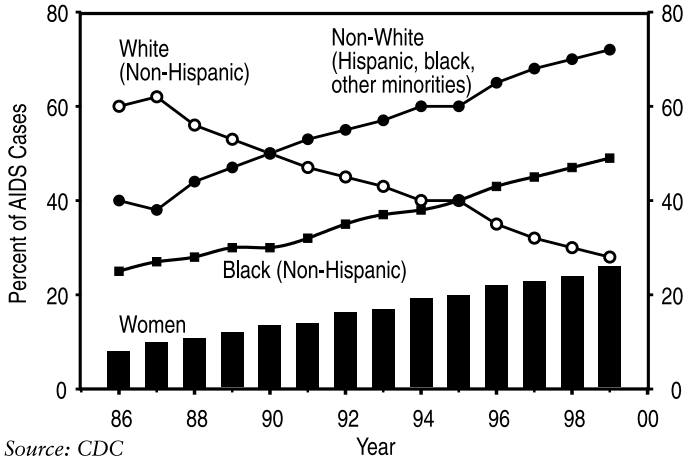
The need for simpler, less toxic, and cheaper drugs and drug regimens to treat HIV infection and its associated opportunistic infections (OIs),

malignancies, and other complications, continues to be a high priority. This includes the discovery and development of the next generations of antiviral drugs directed against new cellular and viral targets. Clinical trials will help to better define when to begin and/or switch drugs within a regimen as well as to identify regimens for treatment-experienced individuals who no longer respond to these anti-HIV drugs. Antiretroviral and OI prophylaxis regimens are becoming increasingly complex with respect to drug-drug interactions and adherence. Protease inhibitors, in particular, interact with each other and many other medications commonly used by HIV-infected individuals. Additional research is under way and planned to address these issues with the goal of minimizing viral replication and delaying disease progression, drug resistance, and development of manifestations such as metabolic complications and body composition changes.

Basic Science

Of paramount importance in our fight against HIV/AIDS is maintaining a strong commitment to basic research. Tremendous progress has been made in understanding the fundamental steps in the life-cycle of HIV, the host-virus relationship, and the clinical manifestations attending HIV infection and AIDS. Groundbreaking research on basic HIV biology and AIDS pathogenesis has revolutionized the design of drugs, the methodologies for diagnosis, and the monitoring for efficacy of antiviral therapies. In spite of these achievements, we still do not have a clear understanding of major aspects of the virus interaction with the infected individual, the nature of the immune response to the virus, how the virus establishes infection and spreads throughout the body, and its mechanisms of pathogenesis. This basic knowledge is critical for our efforts to prevent and control HIV infection and disease progression. In addition, basic behavioral and social science studies are also needed to provide further information on risk factors and behaviors, and the identification of populations at risk. These areas of investigation, driven by investigators-initiated research, have provided the constantly advancing knowledge base that permits the development of new applications for the prevention and

AIDS Incidence by Race and Sex, USA, 1986–1999



Source: CDC

Source: CDC

treatment of HIV/AIDS. Thus, a substantial portion of NIH AIDS-related research will continue to be devoted to fundamental biomedical, behavioral, and social science research.

International Research Priorities

To address the increasing urgency of the global AIDS pandemic, OAR has established a new initiative and strategic plan for global research on HIV/AIDS aimed at slowing the disaster and reversing its destruction of communities, economies, and nations worldwide. The Global AIDS Research Initiative and Strategic Plan reaffirms NIH's long-standing commitment to international AIDS research and will significantly increase research efforts in the coming year to benefit resource- and infrastructure-poor nations. NIH supports a growing portfolio of research conducted in collaboration with investigators in developing countries. Results of this research benefit the people in the country where the research is conducted as well as people affected by HIV/AIDS worldwide. NIH collaborates with UNAIDS, host country Governments, and in-country scientists for vaccine development and in preparations for efficacy trials. NIH-sponsored programs target studies on factors related to HIV transmission and the pathogenic mechanisms associated with HIV disease progression through studies in Africa, Asia, and Latin America. It is critical to the success of international studies that foreign scientists be full and equal partners in the design and conduct of collaborative studies and that they have full responsibility for the conduct of studies in-country. To that end, NIH supports international training programs and initiatives that help to build infrastructure and laboratory capacity in developing countries where the research is conducted.

Racial and Ethnic Minorities

Research to address the disproportionate impact of the HIV/AIDS epidemic on U.S. racial and ethnic minority communities continues to be a high priority. OAR has established the Ad Hoc Working Group on Minority Research to advise us on the scientific priorities in this critical research area, which are reflected in this plan. We are directing increased resources toward new interventions that will have the greatest impact on these groups. These include interventions that address the co-occurrence of other STDs, hepatitis, drug abuse, and mental illness; and interventions that consider the role of culture, family, and other social factors in the transmission and prevention of these disorders in minority communities. NIH is making significant investments to improve research infrastructure and training opportunities for minorities, and we will continue to assure the participation

of minority subjects in AIDS clinical trials as well as in natural history, epidemiologic, and prevention studies. In response to the Congressional Black Caucus initiative, OAR has provided additional funds to projects aimed at: increasing the number of minority investigators conducting behavioral and clinical research; targeting the links between substance abuse, sexual behaviors, and HIV infection; increasing outreach education programs targeting minority physicians and at-risk populations; and expanding our portfolio of population-based research. One of these projects was a Training and Career Development Workshop for racial and ethnic minority investigators. This workshop provided minority investigators with an opportunity to learn about available NIH funding mechanisms and to meet and network with senior minority investigators who receive significant levels of NIH funding.

AIDS Research Benefits Other Diseases

AIDS research is unraveling the mysteries surrounding many other infectious, malignant, neurologic, autoimmune, and metabolic diseases. AIDS research has provided an entirely new paradigm for drug design and development to treat viral infections. For example, the drug known as 3TC, developed to treat AIDS, is now the most effective therapy for chronic hepatitis B infection. Drugs developed to prevent and treat AIDS-associated OIs also provide benefit to patients undergoing cancer chemotherapy or receiving anti-transplant rejection therapy. AIDS is also providing new understanding of the relationship between viruses and cancer.

THE NIH AIDS RESEARCH PROGRAM

The Role of the Institutes

Each NIH component supports HIV/AIDS-related research activities, consistent with its individual mission. A list of the NIH ICs is found in Appendix A of this Plan. The ICs whose research programs are most heavily concerned with HIV, AIDS, and their sequelae are the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), the National Center for Research Resources (NCRR), the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute of Child Health and Human Development (NICHD). A table of expenditures by IC appears in Appendix B. The Warren Grant Magnuson Clinical Center provides the infrastructure for intramural clinical studies sponsored by the ICs.

The Role of the Office of AIDS Research

OAR was established in 1988 by the Director of NIH and the Department of Health and Human Services (DHHS) Assistant Secretary of Health to coordinate the AIDS research effort across NIH and serve as a focal point for AIDS policy and budget development. The NIH Revitalization Act of 1993 (Public Law 103-43) gave broad new authorities to the office. OAR is responsible for the annual comprehensive planning and budgeting process for all NIH AIDS research and for preparation of a Presidential bypass budget. The law also requires OAR to evaluate the AIDS activities of each of the ICs, as well as provide for the periodic reevaluation of such activities. OAR maintains a discretionary fund, and the appropriations committees have provided OAR with transfer authority permitting it to move up to 3 percent of AIDS research funds among Institutes. The OAR monitors and fosters plans for NIH involvement in international AIDS research activities.

OAR has established and supported the efforts of five trans-NIH Coordinating Committees in the following areas: Natural History and Epidemiology, Etiology and Pathogenesis, Therapeutics, Vaccines, and Behavioral and Social Science. The Committees represent those Institutes with the most significant research portfolios in these areas. The Committees foster collaboration and coordination and assist in the development of the NIH Plan and budget for AIDS research. In addition, OAR established the Ad Hoc Minority Working Group in 1999. Composed of NIH staff and non-NIH scientists and experts, this group advises the OAR Director on needed research and research-related efforts specifically targeted to these populations. OAR also established the Global AIDS Research Strategy Group to bring together all of the NIH ICs with international AIDS research portfolios, the Centers for Disease Control and Prevention, and the U.S. Agency for International Development, to facilitate international research efforts.

To carry out its activities, OAR depends upon the expert advice of several committees. Each of these committees includes AIDS community representatives. The OAR Advisory Council (OARAC) is composed of non-Government experts from a broad array of disciplines, as well as AIDS community representatives. OARAC reviews the annual Plan and discretionary fund disbursements. A list of current OARAC members is included as Appendix C. OAR also has established the Prevention Science Working Group and the Therapeutics Research Working Group to provide advice in these critical scientific areas.

OAR directly supports several programs and initiatives. These include the Intramural AIDS Targeted Antiviral Program (IATAP) and the NIH AIDS Research Loan Repayment Program (LRP). In addition, OAR recognizes the critical need to ensure that research results are translated into effective prevention programs and into clinical practice. To accomplish this goal, OAR supports a number of activities to promote the distribution of research information to researchers, physicians, institutions, and communities.

OVERVIEW OF THE PLAN

The Planning Process

OAR has established a unique and effective model for developing a consensus on scientific priorities for the annual comprehensive NIH Plan for HIV-Related Research. To develop the FY 2003 Plan, OAR sponsored a series of Planning Workshops to seek the input of non-NIH experts, including scientists from academia, foundations, and industry, and community representatives. These experts participated with NIH scientific and program staff in Planning Groups for Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; Behavioral and Social Science; Microbicides; HIV Prevention Research; Racial and Ethnic Minorities; Women & Girls and HIV/AIDS Research, and International Research. A list of participants in the Planning Groups is found in their respective sections of the FY 2003 Plan. Participants in each Planning Group were asked to review and revise the objectives and strategies of the draft Plan, based on the state of the science, and to identify a set of priorities for their area. All groups were asked to address needs in the areas of information dissemination, training, infrastructure and capacity building related to their area. The resulting draft Plan was then provided to each IC Director and AIDS Coordinator for recommendations and comments. Finally, the Plan was reviewed by the OARAC.

OAR continues to reassess the planning process and make refinements in order to better capture the broadest range of expertise and community participation and to facilitate the identification of specific scientific priorities. This year, new sections have been added to the Plan, focusing on Microbicides; HIV Prevention Research; and Women & Girls and HIV/AIDS Research.

Structure of the Plan

The Plan is divided into 12 Areas of Emphasis: Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; Behavioral and Social Science; Microbicides; HIV Prevention Research; Racial and Ethnic Minorities; Women & Girls and HIV/AIDS Research;

International Research; Training, Infrastructure, and Capacity Building; and Information Dissemination. The structure of the plan is designed to (1) comprehensively describe research activities that are needed to address HIV and AIDS; (2) define specific research priorities; and (3) reflect mutual reinforcement among the Scientific Areas of Emphasis.

Scientific Issues and Priorities

This section provides a scientific overview and specific priorities identified by the planning groups for each area. These priorities narrowly define a few high-priority areas deemed most worthy of new or expanded funding, based on the current scientific knowledge, opportunities, and gaps. They will be used to guide the development of the FY 2003 AIDS budget and to adjust the FY 2002 AIDS budget as needed. It is expected that these priorities will change from year to year, and thus expenditures in these areas will not be tracked over time.

Objectives and Strategies

Objectives consist of a comprehensive list, in priority order, of the scientific questions to be addressed for each Scientific Area of Emphasis. Under each Objective is a set of Strategies that provide examples of avenues and approaches that may be pursued.

Uses of the Plan

The Plan serves several purposes:

- As the framework for developing the NIH AIDS budget. A chart showing the interaction between the planning and budget process may be found in Appendix E.
- For determining the use of NIH AIDS-designated dollars and for tracking and monitoring those expenditures. The Plan thus defines those research areas for which AIDS-designated funds may be allocated.
- As a document that provides information to the public, the scientific community, Congress, and the AIDS-affected communities about the NIH AIDS research agenda. OAR distributes the annual comprehensive Plan to a wide audience, and it appears on the OAR Web site: http://www.nih.gov/od/oar/.

APPENDIX A:

NIH Institutes and Centers

NIH INSTITUTES AND CENTERS

NCI	National Cancer Institute
NEI	National Eye Institute
NHLBI	National Heart, Lung, and Blood Institute
NHGRI	National Human Genome Research Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NICHD	National Institute of Child Health and Human Development
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NINDS	National Institute of Neurological Disorders and Stroke
NIDA	National Institute on Drug Abuse
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIMH	National Institute of Mental Health
NINR	National Institute of Nursing Research
NLM	National Library of Medicine
CC	Warren Grant Magnuson Clinical Center
CIT	Center for Information Technology
NCCAM	National Center for Complementary and Alternative Medicine
NCRR	National Center for Research Resources
FIC	Fogarty International Center
CSR	Center for Scientific Review
NCMHD	National Center on Minority Health and Health Disparities
NIBIB	National Institute of Biomedical Imaging and Bioengineering

APPENDIX B:

Summary of HIV/AIDS Funding

HIV/AIDS FUNDING BY NIH INSTITUTE, CENTER, AND OFFICE

Institute/Center	FY 2000 Actual	FY 2001 Estimate	FY 2002 Request
NCI	$230,474,000	$237,860,000	$251,200,000
NHLBI	65,527,000	68,008,000	71,717,000
NIDCR	20,193,000	21,862,000	22,937,000
NIDDK	21,983,000	24,562,000	27,360,000
NINDS	33,621,000	37,674,000	42,264,000
NIAID	928,695,000	1,062,592,000	1,192,855,000
NIGMS	37,128,000	43,298,000	47,891,000
NICHD	89,540,000	101,666,000	114,496,000
NEI	10,890,000	11,555,000	12,730,000
NIEHS	7,541,000	7,769,000	8,166,000
NIA	3,919,000	4,386,000	4,985,000
NIAMS	5,022,000	5,629,000	6,404,000
NIDCD	1,590,000	1,592,000	1,596,000
NIMH	128,562,000	145,051,000	161,417,000
NIDA	217,898,000	244,902,000	284,741,000
NIAAA	19,218,000	21,195,000	24,402,000
NINR	7,501,000	9,663,000	10,978,000
NHGRI	4,188,000	5,750,000	6,158,000
NIBIB	—	—	—
NCRR	105,788,000	117,410,000	129,112,000
NCCAM	1,030,000	1,030,000	1,630,000
NCMHD	—	—	—
FIC	14,404,000	16,152,000	18,096,000
NLM	5,063,000	5,525,000	6,677,000
OD	44,653,000	48,234,000	53,540,000
B&F	—	—	—
TOTAL	$2,004,428,000	$2,243,365,000	$2,501,352,000

APPENDIX C:

Office of AIDS Research Advisory Council

OFFICE OF AIDS RESEARCH ADVISORY COUNCIL

Chair

Catherine M. Wilfert, M.D.
Scientific Director
Elizabeth Glaser Pediatric AIDS Foundation

Executive Secretary

Jack Whitescarver, Ph.D.
Acting Director
Office of AIDS Research, NIH

Members

Constance A. Benson, M.D.
Vice Chair
Adult ACTG Executive Committee
Professor of Medicine
Division of Infectious Diseases
University of Colorado Health Sciences Center

Robert E. Booth, Ph.D.
Professor
Department of Psychiatry
Division of Substance Dependency
University of Colorado Health Sciences Center
School of Medicine

Gina M. Brown, M.D.
Assistant Professor
Department of Obstetrics/Gynecology
Women's Medical Director
Women and Children Care Center
Columbia University College of Physicians and Surgeons
Columbia Presbyterian Medical Center

Peter C. Doherty, Ph.D.
Chair
Department of Immunology
St. Jude Children's Research Hospital

Mr. Gregg Gonsalves
Director of Treatment Advocacy
Gay Men's Health Crisis

Lawrence O. Gostin, L.L.D., J.D.
Professor of Law
Co-Director
Program on Law and Public Health
Georgetown University Law Center
Georgetown/Johns Hopkins University

Philip D. Greenberg, M.D.
Professor of Medicine
Division of Oncology
University of Washington School of Medicine

John B. Jemmott III, Ph.D.
Kenneth B. Clark Professor of Communication
Annenberg School for Communication
University of Pennsylvania

Ms. Miguelina Ileana León
Director
Government Relations and Policy
National Minority AIDS Council

Michael K. Lindsay, M.D., M.P.H.
Director
Division of Maternal Fetal Medicine
Associate Professor
Department of Gynecology and Obstetrics
Emory University School of Medicine
Grady Memorial Hospital

Julie Overbaugh, Ph.D.
Member
Division of Human Biology
Fred Hutchinson Cancer Research Center

Ms. Sallie Marie Perryman
Project Manager of Educational Services
New York State Department of Health AIDS Institute

Eve E. Slater, M.D.
Senior Vice President
Merck & Company, Inc.

Mr. William Snow
Board Member
AIDS Vaccine Advocacy Coalition

Sten H. Vermund, M.D., Ph.D.
Professor and Director
John J. Sparkman Center for International Public Health Education
Director
Division of Geographic Medicine
University of Alabama at Birmingham

Mr. Steven F. Wakefield
Director
Community Education
HIV Vaccine Trials Network

Ex Officio Members

Office of the Secretary
Vacant
Director
Office of HIV/AIDS Policy
Office of Public Health and Science
Office of the Secretary
U.S. Department of Health and Human Services

Centers for Disease Control and Prevention
Jim Buehler, M.D.
Associate Director
National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention

U.S. Department of Veterans' Affairs
Lawrence Deyton, M.D., M.S.P.H.
Director of HIV/AIDS Services and Research
U.S. Department of Veterans' Affairs

U.S. Department of Defense
Deborah L. Birx, M.D.
Director
Division of Retrovirology
Walter Reed Army Institute of Research

National Advisory Council on Allergy and Infectious Diseases
Marie Saint Cyr, M.S.W.
Executive Director and Chair
Board of National Minority AIDS Council
Iris House Center for Women

National Cancer Advisory Board
Elmer Huerta, M.D., M.P.H.
Director
Cancer Risk Assessment and Screening Center
Washington Hospital Institute
Washington Hospital Center

National Advisory Council on Drug Abuse
Gerald H. Friedland, M.D.
Director
AIDS Program
Professor of Medicine, Epidemiology, and Public Health
Yale University School of Medicine

National Advisory Mental Health Council
Susan Folkman, Ph.D.
Professor
Department of Medicine
Center for AIDS Prevention Studies
University of California, San Francisco

APPENDIX D:

List of Acronyms

LIST OF ACRONYMS

ART	antiretroviral therapy
ACTIS	AIDS Clinical Trials Information Service
AIDS	acquired immunodeficiency syndrome
AITRP	AIDS International Training and Research Program, FIC
ATI	Analytic Treatment Interruption
ATIS	HIV/AIDS Treatment Information Service
AVEG/HVTN	AIDS Vaccine Evaluation Group/HIV Vaccine Trials Network
BSL	biosafety level
B/START	Behavioral Science Track Award for Rapid Transition
CAB	community advisory board
CBO	community-based organizations
CDC	Centers for Disease Control and Prevention
CFAR	Centers for AIDS Research
CIPRA	Comprehensive International Programs in Research on AIDS
CMV	cytomegalovirus
CNS	central nervous system
CSF	cerebrospinal fluid
CTL	cytotoxic T lymphocytes
DC	dendritic cell
DHHS	Department of Health and Human Services
DNA	deoxyribonucleic acid
DOT	directly observed therapy
EBV	Epstein-Barr virus
FDA	Food and Drug Administration
FIRCA	Fogarty International Research Collaboration Award, FIC
GCP	Good Clinical Practices
GCRC	General Clinical Research Center
GI	gastrointestinal

GLP/GMP	good laboratory practices/good manufacturing production
HAART	highly active antiretroviral therapy
HBCU	Historically Black Colleges and Unviersities
HBV	hepatitis B virus
HCFA	Health Care Financing Administration
HCV	hepatitis C virus
HERS	HIV Epidemiology Research Study
HHV	human herpes virus
HIV	human immunodeficiency virus
HPTN	HIV Prevention Trial Network
HPV	human papillomavirus
HRSA	Health Resources and Services Administration
HVTN	HIV Vaccine Trials Network
IC	Institute and Center
ICC	invasive cervical cancer
IDU	injecting drug user
IHS	Indian Health Service
IUD	intrauterine device
JCV	JC virus
KS	Kaposi's sarcoma
KSHV	Kaposi's sarcoma herpes virus
LRP	Loan Repayment Program, NIH
MAC	*Mycobacterium avium* complex
MCT	mother-to-child transmission
MDR-TB	multiple drug-resistant tuberculosis
MHC	major histocompatibility complex
MSM	men who have sex with men
N9	nonoxynol
NAFEO	National Association for Equal Opportunity in Higher Education
NGO	nongovernment organizations

NHL	non-Hodgkin's lymphoma
NHP	non-human primate
NIH	National Institutes of Health
NRTIs	nucleoside reverse transcriptase inhibitors
OAR	Office of AIDS Research, NIH
OARAC	Office of AIDS Research Advisory Council
OD	Office of the Director, NIH
OI	opportunistic infection
PHS	Public Health Service
PML	progressive multifocal leukoencephalopathy
RCMI	Research Center in Minority Institution
RCT	randomized clinical trials
RFIP	Research Facilities Infrastructure Program
RNA	ribonucleic acid
RPRC	Regional Primate Research Center
SAMHSA	Substance Abuse and Mental Health Services Administration
SCID	severe combined immunodeficiency
SHIV	chimeric simian/human immunodeficiency virus
SIT	scheduled intermittent therapy
SIV	simian immunodeficiency virus
SPF	specific pathogen-free
STD	sexually transmitted disease
STI	Structured Treatment Interruption
TB	tuberculosis
TI	treatment interruption
UNAIDS	United Nations Joint Programme on AIDS
VEE	Venezuelan equine encephalitis virus
VRC	Vaccine Research Center
WHO	World Health Organization
WIHS	Women's Interagency HIV Study

APPENDIX E:

FY 2003 Plan and Budget Timeline

OAR ANNUAL PLAN AND BUDGET PROCESS
FY 2003 Timeline

PLAN	
February 2001	Draft 1 — External Consultants NIH Program Staff IC AIDS Coordinators IC Directors
March 2001	Draft 2 — OAR Advisory Council Comments
July 2001	Final Plan Published
BUDGET	
May 2001	ICs Prepare Budget Using Draft Plan
June 2001	Draft Budget Developed Based on IC Request
August 2001	AIDS Budget Submitted to Director, NIH
August-December 2001	NIH Budget to Secretary, DHHS DHHS Budget to OMB
February 2002	FY 2003 President's Budget to Congress
March 2002	Appropriations Subcommittee Hearings
April-September 2002	House, Senate, Conference Action
October 2002	FY 2003 Begins

Office of AIDS Research, National Institutes of Health
Building 2, Room 4W01 (MSC 0255)
Two Center Drive, Bethesda, Maryland 20892
Tel: 301-402-8655, Fax: 301-402-8638

Additional copies are available on the OAR Web site
oar.od.nih.gov